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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,571	11/20/2003	Volker Schellenberger	GC560-D1-C1	3420

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/719,571	SCHELLENBERGER ET AL.
	Examiner	Art Unit
	Maria B Marvich, PhD	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 November 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 49-71 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 49-71 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 November 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/20/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

This office action is in response to a preliminary amendment filed 11/20/03.

Claims 1-49 have been canceled and claims 49-71 have been added.

Information Disclosure Statement

An IDS filed 11/20/03 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Priority

The instant application claims benefit to non-provisional application 10/037677. The current status of the nonprovisional parent application referenced should be updated.

Specification

The disclosure is objected to because of the following informalities: while applicants have amended the specification to add ATCC accession numbers for the corresponding deposited biological material, the designations for the organism on page 11, line 18 is missing.

Figure 2 has four parts labeled 2A-d. However, the brief description of figure 2 only includes a description of parts A and B. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d

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1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 49 and 61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 of U.S. Patent No. 6,365,410.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in 6,365,410. That is, the cited claims of 6,365,410 anticipate and fall entirely within the scope of the rejected claims of the instant application. Both the claim in the 6,365,410 patent and the instant claims 49, 56, 58-61, 67-68 and 70 recite the exact same method steps. However, the claims differ in that claims 1-10 in the 6,705,503 recites in the preamble that the method is directed to preparation of an evolved microorganism whereas the claims in the instant application recite in the preamble that the method is for producing a protein. Additionally, claim 3 cannot be considered patentably distinct over claim 49 or claim 55 because it would have been obvious to one of ordinary skill to modify the method of claim 3 from patent 6,329,176 by also reciting that the microorganism to be cultured is also obtained to thus generate the instant invention. The ordinary skilled artisan would have been motivated to do this as the embodiment of also obtaining a microorganism is essential to the invention and the invention cannot be performed without also obtaining a microorganism. Given the teachings of the claims in

6,365,410 and the level of skill of the ordinary skilled artisan at the time of the invention, a reasonable expectation of success in practicing the claimed invention for evolved microorganism production would have been expected.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,365,410 patent, then two different assignees would hold a patent to the claimed invention of 6,365,410, and thus improperly there would be possible harassment by multiple assignees.

Claim 49, 52-54, 56-57, 59 and 61-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,705,503.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in 6,705,503. That is, the cited claims of 6,705,503 anticipate and fall entirely within the scope of the rejected claims of the instant application. Both the claim in the 6,705,503 patent and the instant claims 49, 52-54, 56-57, 59 and 61-64 recite the exact same method steps. However, the claims differ in that claims 1-10 in the 6,705,503 recites in the preamble that the method is directed to preparation of an evolved microorganism whereas the claims in the instant application recite in the preamble that the method is for producing a protein.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,705,503 patent, then

two different assignees would hold a patent to the claimed invention of 6,705,503, and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations that the evolved microorganism is used “for producing a protein” has been added to claim. Similarly, the step of expressing and isolating the protein has been added to the claims. Applicant has not indicated where support for this limitation is found. The examiner has been unable to find literal support in the originally filed specification for the terms “producing” “expresses” or “isolating” the heterologous protein. Therefore, the limitation s that the heterologous protein is “produced” and the , the step of expressing and isolating the protein is impermissible NEW MATTER.

Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant invention recites a genus of mutator genes selected from the group consisting of *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS* and *mutU* mutations or homologues thereof.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants teach that a mutator gene is a DNA repair gene with a mutation. For the development of evolved microorganisms, applicants generate sixteen plasmids comprising mutations in *mutD* (see table 1). These plasmids are used to transform target organism and are further exposed to conditions that generate evolved microorganisms. With the exception of the nucleic acid and amino acid sequences for *mutD*, the specification does not disclose any of the sequences of the recited genes nor provide a description of the genes such that the structural requirements of the genes can be envisioned. The prior art does not teach structural analysis of the recited genes. Applicants have not clearly identified the genes that belong to this genus except by disclosing that a homologue refers to a functionally related DNA repair gene (page 7, line 16). Neither the prior art nor the specification has provided adequate written description to support or illustrate the genus encompassed by the claim. Given the absence of disclosed or art recognized correlations between structure and function of homologues of

mut genes, the large number of potential homologues that can be generated in said genes and the uncertainty that any homologue will be functional, it must be considered that any homologue must be empirically determined. By disclosing *mutD* mutations, the applicants have not reduced to practice homologues of *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, *mutU* mutations. Given the diversity of the recited mutator genes, the absence of disclosed or art recognized structure-function relationships and the unpredictability of the art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 49, 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is vague and indefinite in that the metes and bounds of “a method for producing a protein”. The method as recited does not set forth any steps for the production of a protein.

Claim 53 is vague and indefinite in that the metes and bounds of “the mutator gene” are unclear. The mutator gene is selected from the group consisting of *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS* and *mutU* mutations. A mutator gene is a DNA repair gene with a mutation. However, the previous list of genes encode wild type DNA repair proteins and as recited, it is unclear how the genes can be mutator genes.

Claim 53 is vague and indefinite in that the metes and bounds of “*mutU* mutations” are unclear. It is unclear *mutU* mutations can be a mutator genes. Mutations *mutU* can generate a mutator gene but the mutations themselves cannot be mutator genes.

Conclusion

Claims 49-71 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00). If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

August 20, 2004


GERRY LEFFERS
PRIMARY EXAMINER